REMARKS

## I. Status of the Claims

Claims 2, 6, 7, 11-13, 18, and 20 are pending in this application. No claims have been amended.

## II. Rejection of Claims under 35 U.S.C. § 112

Claims 2, 6, 7, 11-13, 18, and 20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully disagree, as claims 2, 6, and 11 are adequately described in the specification as originally filed.

Claim 2 is directed to a method of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition. The method comprises administering to the individual an effective amount of a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid.

Claim 6 is directed to a method of reducing the level of an inflammatory marker in an individual subject to end-stage renal disease. The method comprises administering to the individual a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid in an effective amount.

Claim 11 is directed to a method for ameliorating a symptom of an inflammatory condition in an individual subject to an inflammatory condition. The method comprises administering to the individual a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, in an amount effective to reduce the level of an inflammatory marker associated with said inflammatory condition.

The description in a patent application as filed is **presumed** to be adequate for purposes of satisfying the written description requirement. (See, e.g., MPEP §2163.04). As a result, the Office has the initial burden of establishing, by a **preponderance of the evidence**, why a person of ordinary skill in the art would not recognize in the application as filed a description of the

invention defined by the claims. Applicants respectfully submit the Office has failed to satisfy that burden.

The Office asserts there is no description how reducing the level of C-reactive protein in an individual subject to a CRP associated inflammatory condition comprising administering to the individual an effective amount of a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid is related to reducing the level of an inflammatory marker in an individual subject to end-stage renal disease or the inflammatory marker is CRP, or ameliorating a symptom of an inflammatory condition, cardiovascular inflammatory condition, respiratory inflammatory condition, sepsis, diabetes, muscle fatigue, systemic lupus erythematosis (SLE), end stage renal disease (ESRD), premenstrual syndrome (PMS), and periodontal disease in an individual subject to an inflammatory condition or when the inflammatory marker is CRP or IL-6. Applicants respectfully disagree.

Applicants submit that the claims are directed to methods comprising administering a composition comprising an effective amount of 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid. The specification provides a detailed discussion of inflammation and inflammation associated with inflammatory markers such as, for example, CRP and IL-6.[1] Moreover, the specification provides definitions for the terms "a CRP associated inflammatory condition",[2] "amelioration",[3] and "an effective amount"[4]. The specification also provides that "[e]levated levels of C-reactive protein (CRP) have been associated with various inflammatory conditions."[5] Therefore, Applicants submit that the claims are related as being directed to methods comprising administering a composition comprising an effective amount of 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid for reducing or ameliorating an inflammatory marker for example, CRP, in an inflammatory condition, for example end-stage renal disease or an inflammatory condition, cardiovascular inflammatory condition, respiratory

[1] Specification at p. 5, lines 8-32 and p. 9, line 1 - p.10, line 27.
[2] *Id.* at p. 5, lines 18-32.
[3] *Id.* at p. 6, lines 9-11.
[4] *Id.* at p. 6, lines 1-6.
[5] *Id.* at p. 5, lines 17-18.

inflammatory condition, sepsis, diabetes, muscle fatigue, systemic lupus erythematosis (SLE), end stage renal disease (ESRD), premenstrual syndrome (PMS), and periodontal disease.

The Office also asserts on page 5 of the Office action that indistinct terms may not suffice to meet the written description requirement (citing *Univ. of Rochester v. G.D. Searle*[6]). Applicants submit that unlike in *Univ. of Rochester* where the claims recited "a non-steroidal compound" that the court found to be a generic structural term and where the patentee did not describe any specific non-steroidal compounds, claims 2, 6, and 11 require administering an effective amount of the specific compound 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid. The claims also describe 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid in functional terms such as, for example, reducing the level of CRP, reducing the level of an inflammatory marker, and ameliorating a symptom of an inflammatory condition.[7] The specification defines the meaning of an effective amount[8] and describes amelioration as at least about 30% reduction in CRP levels.[9]

Additionally, Example 1 demonstrates the reduction of CRP levels by 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid. Specifically, Example 1A provides exemplary assays for measuring inflammatory reaction in a cell line in order to provide a predictive measure of anti-inflammatory activity of compositions of the present invention; that is, Example 1A provides a method for determining if the compositions of the present invention, and specifically if a composition including either 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid methyl ester or **3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid** could effectively reduce the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition. As shown on page 18, lines 27-31, 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, at an $EC_{50}$ of between about 40 to about 60 μM, was effective at reducing CRP levels.[10] Thus, unlike in *Univ. of Rochester* cited by the Office, Applicants submit that one skilled in the art would understand from reading the specification of the instant

[6] *Univ. of Rochester v. G.D. Searle*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004).
[7] Specification at p. 11, lines 13-18.
[8] *Id.* at p. 6, lines 1-6.
[9] *Id.* at p. 6, line 6.
[10] *Id.* at p. 18, lines 27-31.

application that effective amounts of the compound 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid are used to practice the claimed methods of reducing the level of CRP, reducing the level of an inflammatory marker, and ameliorating a symptom of an inflammatory condition.

Based on the foregoing, Applicants submit that the language of claims 2, 6, and 11 is clearly supported by the specification of the application as filed. Applicants further submit that one of ordinary skill in the art would recognize that Applicants were in possession of the subject matter of claims 2, 6, and 11 as of the filing date of the present application. Furthermore, Applicants respectfully disagree with the Office's assertion that the possible compounds cover a large number of compounds having widely divergent structures and functions. (See the Office action at page 6.) To the contrary, the requirements of claims 2, 6, and 11, taken as a whole, provide both function and structure. Specifically, the structural and functional details are provided for 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid for reducing the level of an inflammatory marker.

Accordingly, Applicants respectfully submit that claims 2, 6, and 11 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the present rejection is therefore respectfully requested.

Because claims 7, 12, 13, 18, and 20 directly or indirectly depend from claims 2, 6, and/or 11, it is submitted that these claims satisfy the written description requirement for at least the same reasons as set forth with respect to claims 2, 6, and 11, as well as the other requirements recited therein. In particular, it is submitted that (i) claims 12 and 18, which further specify the inflammatory marker and (ii) claim 13, which further specifies the inflammatory condition, satisfy the written description requirement, in view of the specificity recited therein.

## CONCLUSION

In view of the foregoing, Applicant respectfully requests favorable reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge any fees due to Deposit Account 01-2384 in the name of Armstrong Teasdale LLP.

Respectfully submitted,

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Via EFS